

## CORRESPONDENCE

### Solid phase immunoassay for *C trachomatis*

The development of chlamydial antigen detection kits has led to the wider availability of diagnostic services for this organism. Currently, two technologies are readily available; immunofluorescence microscopy and enzyme linked immunosorbant assay (EIA). Neither technology is perfect, with problems of sensitivity and of specificity.<sup>1</sup> Advances continue, and it is important that new kits are properly evaluated against chlamydial cell culture in both high and low risk populations.

Solid phase immunoassay (IA) tests are simple to use, requiring little technical expertise. They are likely to become popular as "office" tests. We recently evaluated the performance of a novel IA utilising coloured latex particles (Clearview Chlamydia, Unipath, Bedford, UK) for cervical specimens against conventional cell culture.

Specimens from the cervix of 148 women attending the Genitourinary Medicine Departments of the Middlesex Hospital and University College Hospital were examined. Two cotton tipped swabs were taken from the cervix, one was expressed into 2SP transport medium for chlamydial culture, and the other was used for immuno-assay. The order of taking the swabs was determined from a random number table.

Chlamydial culture utilised cycloheximide treated McCoy cells, grown on glass coverslips in plastic vials. All specimens were inoculated in duplicate, and one of each pair sub-

jected to a single blind passage. The presence of *Chlamydia trachomatis* was confirmed using a specific immunofluorescent monoclonal antibody stain (Microtrak, Syva Cor., Palo Alto, Calif.).

Swabs for immunoassay were processed according to the manufacturers' instructions. In brief, the swab plus extraction reagent were held at 80°C for 10 minutes. The swab was then discarded. After cooling, 5 drops of the extract were added to the sample window of the test unit. The appearance of a blue/black line in the result window within 15 minutes was taken to indicate the presence of chlamydial antigen (positive and negative controls were included in each batch). Discrepant results were further evaluated by application of the Syva Microtrak Direct Immunofluorescence (DIF) test to the remaining immunoassay extract, and examining for stained elementary bodies.

*C. trachomatis* was isolated from 34 of 148 women (23%). There were seven discrepant results (see table), all were culture positive, immunoassay negative. One of the seven (immunoassay swab taken first) was positive with the Microtrak DIF test. The other six were all randomised to have the immunoassay swab taken second, and were negative on DIF. This could reflect low levels of antigen on the swab. The sensitivity, specificity, predictive value of a positive result (PVP), predictive value of a negative result (PVN), and agreement were 79.4%, 100%, 100%, 94.2% and 95.27%, respectively, for the Clearview immuno-assay compared with cell culture.

In our hands, the Clearview Chlamydia immunoassay test compares favourably with other immunoassays evaluated against our cell culture system. We found that sensitivity was low compared to our results for the Abbott Chlamydiazyme,<sup>2</sup> and Pharmacia EIA<sup>3</sup> tests (92.3%, 90.5%, respectively), and indeed lower than the 93.5% sensitivity reported by Arumainayagam *et al*<sup>4</sup> in a recently reported comparison of Clearview against cell culture. A similar degree of sensitivity was found with the Ortho Chlamydia EIA test (80%).<sup>5</sup> Specificity and PVP were excellent, as reported by Arumainayagam and co-workers. This indicates that the test will be reliable for both high and low

risk populations. However, the lower sensitivity compared to other enzyme immunoassays may restrict its use in the latter group. The test was simple to use, requiring a dry swab without the need for a special transport medium. The test took an average of 40 minutes to perform, and the endpoint was clear.

The test is not as yet available for use on specimens from the male urethra, or other sites.

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Table Comparison of immuno-assay (Clearview Chlamydia) with cell culture for detecting cervical chlamydial infection

Incidence (by cell culture) = 34/148 = 23.0%

	Cell culture	
	Pos	Neg
CLEARVIEW IMMUNOASSAY		
Pos	27	0
Neg	7	114

### Susceptibility of *Haemophilus ducreyi* to spermicidal compounds, in vitro

The active ingredients of spermicidal preparations are known to have antimicrobial activity against most of the causative organisms of sexually transmitted diseases, in vitro<sup>1</sup> and clinical studies have also confirmed that spermicides can provide effective prophylaxis against the infections in vivo.<sup>2</sup> *Haemophilus ducreyi* is endemic in many African and other third-world countries where it is the commonest

Table Minimum inhibitory concentrations of spermicidal compounds for seven *H ducreyi* strains

<i>H ducreyi</i> strain no.	MIC (mg/l) of spermicidal compounds				
	Non-ionic			Cationic	Anionic
	Nonoxynol-9	Nonoxynol-11	Menfegol	Benzalkonium chloride	Docusate sodium
NCTC 11479	78	78	78	≤ 19	39
NCTC 11480	156	78	39	≤ 19	39
NCTC 11482	156	156	39	≤ 19	39
NCTC 11483	156	78	78	≤ 19	39
NCTC 11484	1,250	5,000	5,000	≤ 39	2,500
NCTC 11616	615	> 10,000	10,000	≤ 39	78
NCTC 10945	156	156	156	≤ 19	39
Range	78–1250	78–> 10,000	39–10,000	≤ 19–39	39–2,500
MIC 50	156	156	78	≤ 19	39
MIC 90	625	5,000	5,000	39	78

cause of genital ulcer disease and evidence is emerging that it may also be a co-factor in the transmission of Acquired Immunodeficiency Syndrome (HIV)<sup>3</sup> which is a heterosexual problem in these countries. Studies in Nairobi<sup>4</sup> have shown that genital ulcers increase the risk of seropositivity in males and that, being uncircumcised and having sexual contact with a prostitute are additional risk factors. Female studies<sup>5</sup> also showed that genital ulcer disease was a major risk of HIV infection, probably due to the ulcerative disruption of the mucosal lining of the vagina, allowing the virus ready access from infected semen.

We have determined the susceptibility of *H ducreyi* to five spermicidal compounds, kindly supplied by the London International Group, PLC, in an agar dilution technique. They were incorporated into Sheffield medium<sup>6</sup>, supplemented with 5% defibrinated horse blood at concentrations ranging from 10,000 to 19 mg/l. Eight strains of *H ducreyi* were obtained from the

National Collection of Type Cultures and smooth suspensions containing 10<sup>9</sup> cfu per ml were prepared by sonication. 10<sup>6</sup> cfu were then delivered to the agar surfaces by Multipoint inoculator and the plates incubated at 33°C, in 5% CO<sub>2</sub> in air for 4 days. MICs were recorded as the lowest concentration of spermicide that prevented visible growth.

The results showed that *H ducreyi* was highly susceptible to the spermicides tested (table), and that the concentrations incorporated into condom lubricants or vaginal inserts are far in excess of these MICs for this organism. Their usage could, therefore, exert a significant antimicrobial effect against *H ducreyi*, in vivo and consequently be a useful additional preventative factor in the transmission of HIV infection.

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### Failure of single dose ceftriaxone in donovanosis (granuloma inguinale)

Female to male transmission of HIV is enhanced by the presence of genital mucosal discontinuity<sup>1</sup> and the continued spread of the epidemic in sub-Saharan Africa is likely to be closely related to the control of genital ulcer disease (GUD). Single dose ceftriaxone for chancroid and treatment against syphilis are recommended in the management of GUD in areas

where facilities are limited.<sup>2</sup> However, such a regime is untested in areas where donovanosis is prevalent. In Durban, where syphilis and chancroid are the most common causes of GUD,<sup>3</sup> donovanosis has recently emerged both as a significant cause of GUD and as a risk factor for HIV-1 infection amongst men.<sup>4</sup> Antibiotic treatment is required for 2–4 weeks and a need exists for therapy of shorter duration to improve patient compliance.

Eight men with donovanosis treated with single dose ceftriaxone 250 mg in

one case and 500 mg in seven, are reported. Donovanosis was diagnosed by the detection of Donovan bodies on tissue smears stained by the Rapidiff technique.<sup>5</sup> Follow-up visits were arranged on day 7 and day 14 following the first attendance when repeat tissue smears were performed. Initial improvement was seen in all eight patients. No intracellular Donovan bodies were detected at follow-up but extracellular organisms were observed after 7 days in two patients, one of whom received ceftriaxone 250 mg